

***CERTIFICATION
EXAMINATION
FOR
IRB
PROFESSIONALS***

Handbook for Candidates

SPRING TESTING PERIOD

Application Deadline: January 15, 2007

First Day of Testing: Saturday, March 3, 2007

Last Day of Testing: Saturday, March 17, 2007

FALL TESTING PERIOD

Application Deadline: August 15, 2007

First Day of Testing: Saturday, September 15, 2007

Last Day of Testing: Saturday, September 29, 2007



PROFESSIONAL TESTING CORPORATION

1350 BROADWAY • 17th FLOOR

NEW YORK, NY 10018

(212) 356-0660

WWW.PTCNY.COM

Code of Ethics

Certified IRB Professionals

The following code of ethics was developed in recognition of the vital role that Certified IRB Professionals play in the ethical conduct of human subject research. It is the responsibility of each Certified IRB Professional to aspire to the highest possible standards of conduct in order to enhance the protection of persons who participate in research.

As a Certified IRB Professional committed to the protection of human research subjects, I will:

- Conduct myself personally and professionally with honesty and integrity at all times to inspire trust and confidence in my actions;
- Give prime consideration to protection of the rights and welfare of research subjects;
- Apply the principles of the Belmont Report and other ethical standards pertaining to the conduct of research involving human subjects;
- Adhere to federal, state and local laws and regulations;
- Respect the rights, dignity and worth of all people and be sensitive to cultural and individual differences;
- Fully disclose or avoid all potential conflicts of interest when rendering professional services, judgements and assessments;
- Avoid using proprietary knowledge or private information for personal gain;
- Ensure that all confidential and private information that comes into my possession is protected;
- Pursue education, network with colleagues and consult with others to develop and maintain the highest possible level of knowledge and understanding;
- Facilitate and encourage open communication among all parties, recognizing the shared responsibility for the ethical conduct of human subject research.

Effective Date: March 23, 2002

All questions about this code of ethics should be addressed to the Council for Certification of IRB Professionals.

CERTIFICATION

The Council for Certification of IRB Professionals (CCIP), an affiliate of Public Responsibility in Medicine and Research (PRIM&R), endorses the concept of voluntary, periodic certification by examination for all IRB (Institutional Review Board) professionals. Certification is one part of a process called credentialing. Certification focuses specifically on the individual and is an indication of current knowledge in a specialized area of practice. Certification for IRB professionals is highly valued and provides formal recognition of knowledge of IRB functions and human research protection programs.

PURPOSES OF CERTIFICATION

TO PROMOTE IRB ADMINISTRATION PRACTICE AND TO ADVANCE THE QUALITY OF HUMAN RESEARCH PROTECTION PROGRAMS THROUGH THE CERTIFICATION OF QUALIFIED IRB PROFESSIONALS BY:

1. Recognizing formally those individuals who meet the eligibility requirements of the Council for Certification of IRB Professionals (CCIP) and pass the Certification Examination for IRB Professionals.
2. Encouraging continued personal and professional growth in the practice of human research protection programs.
3. Establishing and measuring the level of knowledge required for certification in IRB administration.
4. Demonstrating a standard level of knowledge about human subject research review under United States rules and regulations; thereby assisting the employer, public, and members of the research professions in the assessment of IRB professionals.

ELIGIBILITY REQUIREMENTS

The certification program is for individuals participating in and overseeing the daily activities associated with an IRB, although other individuals involved in IRB activities who meet the following eligibility requirements are also eligible to take the examination.

1. A Bachelor's degree plus two (2) years of relevant IRB experience within the past seven years*;
OR
Four (4) years of relevant IRB experience within the past ten years*;
OR
Currently certified as a CIP.
2. Completion and filing of an Application for the Certification Examination for IRB Professionals.
3. Payment of required fee.

*Relevant IRB experience must have been substantial and ongoing, represented by a commitment to the area of human subjects protection. Qualifying experience requires performance of IRB functions such as: applying ethical principles and regulations to the review of research protocols and informed consent documents; supporting and/or serving as a resource during IRB meetings; preparation of IRB correspondence and/or documentation; managing the office that provides support of the IRB; training investigators, staff, and IRB members; serving as a human subject protection resource or advisor to investigators, staff, and IRB members; developing IRB policies and procedures; and/or overseeing others in the performance of these activities. IRB chairs and organizational officials who perform these functions may be appropriate candidates for certification. Service as an IRB member is not, in and of itself, sufficient to fulfill the requirements for experience. Likewise, interacting with an IRB as sponsor personnel or study site personnel such as coordinator, administrator or investigator does not fulfill the experience requirements.

ADMINISTRATION

The Certification Program is sponsored by the Council for Certification of IRB Professionals (CCIP), an affiliate of PRIM&R. The Certification Examination for IRB Professionals is administered for the CCIP by the Professional Testing Corporation (PTC), 1350 Broadway - 17th Floor, New York, New York 10018, (212) 356-0660, www.ptcny.com. Questions concerning the examination should be referred to PTC.

ATTAINMENT OF CERTIFICATION AND RECERTIFICATION

Eligible candidates who pass the Certification Examination for IRB Professionals are eligible to use the registered designation CIP after their names and will receive certificates from the CCIP. A registry of Certified IRB Professionals will be maintained by the CCIP and may be reported in its publications.

Certification is recognized for a period of three years at which time the candidate must retake and pass the current Certification Examination for IRB Professionals or meet such alternative requirements as are in effect at that time in order to retain certification.

Recertification must be accomplished prior to the certification expiration to avoid a lapse in certification. Applications to recertify by continuing education must be date stamped by the post office or other documented mode of transmission no later than 30 days after the date of certification lapse or recertification by examination will be required.

A person who holds certification and takes the examination but does not pass, will lose their certification. This is effective on the date that the notification of the results from the examination is received. Also, certification holders should be aware that those who are eligible to recertify by continuing education, but chose to take the examination instead and do not pass may not subsequently use continuing education to recertify. i.e., the examination must be passed before the credential can be reissued.

REVOCATION OF CERTIFICATION

Certification may be revoked by CCIP for any of the following reasons:

1. Falsification of an Application.
2. Misrepresentation of certification status.
3. Violation of the CCIP Code of Ethics.

The Appeals Committee of the CCIP provides an appeal mechanism for challenging revocation of certification. It is the responsibility of the individual to initiate this process by sending a written request to CCIP care of PTC.

APPLICATION PROCEDURE

Obtain a Handbook for Candidates and an Application for the Certification Examination for IRB Professionals from the **Professional Testing Corporation, 1350 Broadway - 17th Floor, New York, New York 10018, (212) 356-0660, www.ptcny.com**.

Read and follow the directions on the Application and in this Handbook for Candidates.

COMPLETION OF APPLICATION

Complete or fill in as appropriate ALL information requested on the Application. Mark only one response unless otherwise indicated.

CANDIDATE INFORMATION: Starting at the top of the Application, print your name, address, daytime phone number, evening phone number, and examination date which you are applying for in the appropriate row of empty boxes.

ELIGIBILITY AND BACKGROUND INFORMATION: All questions must be answered. Mark only one response unless otherwise indicated. Note that training and experience requirement must be completed before submitting your application. Do not submit an application if you have not met the eligibility requirements.

OPTIONAL INFORMATION: These questions are optional. The information requested is to assist in complying with equal opportunity guidelines and will be used only in statistical summaries. Such information will in no way affect your test results.

CANDIDATE SIGNATURE: When you have completed all required information, sign and date the Application in the space provided.

Fold the completed Application. Mail the Application with the appropriate fee (see FEES below) in time to be received by the deadline shown on the cover of this Handbook to:

**CCIP EXAMINATION
PROFESSIONAL TESTING CORPORATION
1350 Broadway – 17th Floor
New York, New York 10018**

NOTE: ALL APPLICATIONS ARE SUBJECT TO AUDIT AND REQUEST FOR SUPPORTING DOCUMENTATION.

FEES

1. Application fee for the Certification Examination for IRB Professionals:

PRIM&R Members	\$335.00
Non-PRIM&R Members.....	\$435.00

MAKE CHECK OR MONEY ORDER PAYABLE TO:

CCIP EXAMINATION

DO NOT SEND CASH.

Visa, MasterCard, and American Express are also accepted. Please complete the credit card payment form on the application.

REFUNDS

There will be no refund of fees. Fees will not be transferred from one testing period to another.

EXAMINATION ADMINISTRATION

The Certification Examination for IRB Professionals is administered during an established two-week testing period on a daily basis, Monday through Saturday, excluding holidays, at computer-based testing facilities managed by LaserGrade Computer Testing, Inc. LaserGrade has over 500 testing sites in the United States as well as other countries. Scheduling is done on a first-come, first-serve basis. To find a testing center near you visit: www.lasergrade.com or call LaserGrade at (800) 211-2754. Please note: Hours and days of availability vary at different centers. You will not be able to schedule your examination appointment until you have received an Eligibility Notice from PTC.

SCHEDULING YOUR EXAMINATION APPOINTMENT

Once your application has been received and processed, and your eligibility verified, you will be mailed an Eligibility Notice. The Eligibility Notice plus photo identification must be presented in order to gain admission to the testing center. **A candidate not receiving an Eligibility Notice or other correspondence at least two weeks before the beginning of the two-week testing period should contact the Professional Testing Corporation by telephone at (212) 356-0660.**

The Eligibility Notice will indicate where to call to schedule your examination appointment as well as the dates in which testing is available. Appointment times are first-come, first-serve, so schedule your appointment as soon as you receive your Eligibility Notice in order to maximize your chance of testing at your preferred location and on your preferred date.

SPECIAL NEEDS

Special testing arrangements may be made for special needs individuals submitting the Application, examination fee, and a letter describing the nature of the disability and the special accommodations needed for testing. Requests for special testing needs individuals must be received at least EIGHT weeks before the testing period begins.

CHANGING YOUR EXAMINATION APPOINTMENT

If you need to cancel your examination appointment or reschedule to a different date within the two-week testing period you must contact LaserGrade at (800) 211-2754 no later than noon, Eastern Standard Time, of the second business day PRIOR to your scheduled appointment.

If you fail to arrive for your appointment or cancel without giving the required notice, you will forfeit your testing fee.

RULES FOR THE EXAMINATION

1. No signaling devices, including cellular phones, pagers, and alarms, may be operative during the examination.
2. No books or other reference materials may be taken into the examination room.

3. No test materials, documents, or memoranda of any sort are to be taken from the examination room.
4. No questions concerning content of the examination may be asked during the testing period. The candidate should read carefully the directions provided on screen at the beginning of the examination session.

REPORT OF RESULTS

Candidates will be notified in writing by PTC within four weeks of the close of the testing period whether they have passed or failed the examination. Scores on the major areas of the examination and on the total examination will be reported. Successful candidates will also receive certificates from the CCIP.

REEXAMINATION

The Certification Examination for IRB Professionals may be taken as often as desired upon filing of a new Application and fee. There is no limit to the number of times the examination may be repeated.

CONFIDENTIALITY

1. The CCIP will release the individual test scores ONLY to the individual candidate.
2. Any questions concerning test results should be referred to Professional Testing Corporation.
3. Names of successful candidates may be published in PRIM&R publications and CCIP documents.
4. Confirmation of CIP status, i.e. certified or not certified, may be provided to persons other than the individual candidate.

CONTENT OF EXAMINATION

1. The Certification Examination for IRB Professionals is a written examination composed of a maximum of 250 multiple-choice, objective questions with a total testing time of four (4) hours.
2. The content for the examination is described in the Content Outline starting on page 7.
3. The questions for the examination are obtained from individuals with expertise in human research protection programs and are reviewed for construction, accuracy, and appropriateness by CCIP.
4. The CCIP, with the advice and assistance of the Professional Testing Corporation, prepares the examination.
5. The Certification Examination for IRB Professionals will be weighted in approximately the following manner:
 - I. Foundations and Concepts of IRB Practice..... 25%
 - II. Organizational and Personnel Knowledge 15%
 - III. IRB Functions and Operations 45%
 - IV. Records and Reports 15%

CONTENT OUTLINE

I. Foundations and Concepts of IRB Practice

- A. Historical Background
- B. Research Ethics
 - 1. Belmont Principles
 - a. Respect for Persons
 - b. Beneficence
 - c. Justice
 - 2. International Codes/Standards
 - a. Nuremberg Code
 - b. Declaration of Helsinki
 - c. Council for International Organizations of Medical Sciences
 - d. International Conference on Harmonisation
 - 3. Professional Codes
 - a. CIP Code of Ethics
 - b. Professional Association Codes
 - 4. Conflict of Interest
- C. Research Design Issues
 - 1. Types of Study Designs
 - 2. Minimizing Risks
 - 3. Study Monitoring (DMC, Plans, etc.)
 - 4. Sample Size/Statistics
 - 5. Privacy and Confidentiality
 - 6. Deception
- D. Regulatory Application
 - 1. HHS Regulations
 - a. Applicability
 - b. Exemptions
 - 2. Common Rule
 - a. Applicability
 - b. Agency Differences
 - c. Exemptions
 - 3. FDA Regulations (Human Subjects)
 - a. Applicability
 - b. Exemptions
 - 4. FDA Regulations (Drugs/Biologics/Devices)
 - a. Applicability
 - b. Exemptions
 - 5. State/Local Regulation
 - 6. Regulatory Audits
 - a. FDA Bioresearch Monitoring Program
 - b. OHRP Monitoring and Site Visits
 - c. Sponsor/Cooperative Group Monitoring
 - d. Joint Commission on Accreditation of Healthcare Organizations
 - 7. Health Insurance Portability and Accountability Act (HIPAA)
- E. Definitions
 - 1. Research
 - 2. Human Subjects
 - 3. Minimal Risk
 - 4. Vulnerable Populations

II. Organizational and Personnel Knowledge

- A. IRB Committee Organization
 - 1. Authority
 - a. Approve/Disapprove/Modify
 - b. Suspend/Terminate
 - 2. Membership Requirements
 - 3. Quorum Requirements
 - 4. Reporting Lines

5. Leadership Issues
- B. IRB Office Organization
 1. Staff Responsibilities and Authorities
 2. Reporting Lines
 3. Management (Personnel, Budget, and Billing)
- C. Institutional Considerations
 1. Scientific Review
 2. Grants and Contracts Review
 3. Other Committee Review (RDRC, Biosafety)
 4. Institutional Review
- D. Educational Program Design/Implementation
 1. Education Programs for IRB Staff
 2. Education Programs for IRB Members
 3. Education Programs for Investigators/Research Sites
4. Education Programs for Institutional Officials

III. IRB Functions and Operations

- A. IRB Review
 1. Levels of Review
 - a. Exempt Procedures
 - b. Expedited Review
 - c. Convened Meeting Review
 2. Types of Review
 - a. Initial Review
 - b. Continuing Review
 - c. Amendment Review
 - d. Adverse Event/ Unanticipated Problems Review
 - e. Final Reports/Study Closure
 3. Criteria for Approval of Research
 - a. Risk Determination and Minimization of Risks
 1. Minimal/Minor Increase/Greater than Minimal
 2. Significant/Non-significant Risk Devices
 3. Procedure Review
 - b. Risk-Benefit Analysis
 - c. Equitable Subject Selection
 1. Inclusion/Exclusion of Children, Minorities and Women
 2. Inclusion/Exclusion of Other Vulnerable Populations
 - d. Informed Consent
 1. General Conditions
 2. Elements
 3. Waiver of Consent
 4. Documentation
 5. Waiver of Documentation
 6. HIPAA
 - e. Monitoring Plans
 - f. Protection of Privacy and Maintenance of Confidentiality
 1. Common Rule
 2. HIPAA
 3. Certificates of Confidentiality
 - g. Additional Safeguards for Vulnerable Subjects
 4. Emergency Uses
 5. Treatment Uses
 6. Subject Recruitment
 - a. Advertisements
 - b. Inclusion/Exclusion Criteria
 - c. Incentives
 7. Special Regulatory Requirements
 - a. Fetuses, Pregnant Women, IVF

- b. Prisoners
 - c. Children
 - d. Emergency-setting Research
 - 8. Data, Documents, Records, Specimens, Repositories
 - 9. International Research
- B. IRB Staff Review
 - 1. Staff Pre-screening
 - 2. Post-meeting Communications/Review
 - 3. Auditing
 - a. IRB office (Internal)
 - b. Investigators/Research Sites
 - c. Program Assessment (TQM/CQI)
- C. Post Approval Monitoring
 - 1. Consent Process
 - 2. Research

IV. Records and Reports

- A. Policies, Procedures and Membership
 - 1. IRB Membership Records
 - 2. IRB Policies
 - 3. IRB Procedures and Forms
- B. Assurances and Registration
 - 1. Federalwide Assurance of Protection for Human Subjects (FWA)
 - 2. IRB Registration
- C. Regulatory Reports (Internal/External)
 - 1. Noncompliance
 - 2. Terminations/Suspensions
 - 3. Subjects' Rights and Welfare (Injury and Adverse Events)
- D. Audit Reports, Monitoring and Other Communications
 - 1. Internal Procedure Audits
 - 2. Study Monitoring Reports
 - 3. External Audits (OHRP, FDA)
 - 4. Accreditation
 - 5. Clinical Trial Registries
- E. Meeting Minutes
 - 1. Attendance, Quorum, Voting
 - 2. Discussion and Findings
 - 3. Reports to the IRB
- F. Document and File Maintenance
 - 1. Study Files
 - 2. IRB Management Files
 - 3. Regulatory Documents
- G. Archiving Requirements
 - 1. IRB Records
 - 2. Investigator Records
 - 3. HIPAA Records
- H. Information Management
 - 1. File Tracking
 - 2. Data Collection
- I. Training Documentation
 - 1. IRB Members and Staff
 - 2. Investigators
 - 3. Institutional Officials

SAMPLE EXAMINATION QUESTIONS

In the following questions, choose the one best answer.

1. According to the Belmont Report, respect for persons typically demands that subjects
 1. share in the benefits of the research.
 2. gain maximum benefit from research.
 3. waive any rights or benefits from research.
 4. enter into research voluntarily with adequate information.

2. Which of the following is used to avoid bias in assigning subjects to experimental groups?
 1. Double blind
 2. Placebo control
 3. Clinical equipoise
 4. Paying subjects to participate

3. In most research, which of the following best assures confidentiality?
 1. Obtaining releases of information
 2. Storing research records in a locked cabinet for at least three years
 3. Following acceptable practices for coding and storing data
 4. Removing identifiers after the research ends

4. When reviewing research, the IRB should ensure that the consent process
 1. includes a consent monitor.
 2. is conducted by a third party.
 3. is the same for all populations.
 4. provides the subject sufficient opportunity to consider whether or not to participate.

CORRECT ANSWERS TO SAMPLE QUESTIONS

1. 4; 2. 1; 3. 3; 4. 4

REFERENCES

The Council for Certification of IRB Professionals (CCIP) has prepared a suggested reference list to assist in preparing for the Certification Examination for IRB Professionals. These references contain journals and textbooks which include information of significance to human research protection programs practice. Inclusion of references on this list does not constitute an endorsement by the CCIP or PRIM&R of specific professional literature which, if used, would guarantee candidates successful passing of the certification examination.

BOOKS

Bankert, E. & Amdur, R. *Institutional Review Board: Management and Function, Second Edition*. Sudbury, MA: Jones and Barlett Publishers, 2006.

Davis, A., et al. *Study Guide for Institutional Review Board: Management and Function, Second Edition*. Sudbury, MA: Jones and Barlett Publishers, 2006.

Dunn, C. & Chadwick, G. *Protecting Study Volunteers in Research: A Manual for Investigative Sites*. (3rd ed.). Boston: Center Watch, 2004.

PERIODICALS

Human Research Report. Omaha, NE. The Deem Corp.

IRB: A review of Human Subjects Research. Briarcliff Manor, NY. The Hastings Center

GUIDANCES

FDA Information Sheets. (1998 ed.). Rockville, MD. Food and Drug Administration

Protecting Human Research Subjects: Institutional Review Board Guidebook. (1993). Bethesda, MD. Office for Protection from Research Risks

REGULATIONS

21 CFR 11

21 CFR 50/56

21 CFR 54

21 CFR 312

21 CFR 600

21 CFR 812

45 CFR 46 (Subparts A, B, C, D)

45 CFR 160/164

OTHER

Ethical Principles and Guidelines for the Protection of Human Subjects of Research (*Belmont Report*)

Declaration of Helsinki

Nuremberg Code

Cooper, J. & Selwitz, A. Investigator 101(CD-ROM), PRIM&R, Boston, MA 2001.

Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Good Clinical Practice

ONLINE RESOURCES

www.primr.org/membership/about.html

www.bioethics.gov

www.fda.gov

www.fda.gov/oc/gcp/

www.hhs.gov/ocr/hipaa/

www.ich.org

www.nih.gov

www.hhs.gov/ohrp

www.thehastingscenter.org

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